UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., and TEVA NEUROSCIENCE, INC., Defendants.	)	Civil Action No. 20-11548

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

TABLE OF CONTENTS

Page

TABLE OF CONTENTS

Page

TABLE OF CONTENTS

Page

TABLE OF CONTENTS

Page

I. INTRODUCTION

The Complaint is premised on the Defendants'[1] donations to two charitable foundations' Multiple Sclerosis ("MS") disease state funds. Those funds helped patients afford medically necessary medication to treat their MS. The government contends that, because Teva allegedly wanted its charitable donations to be used, in whole or in part, to help MS patients afford Teva's MS medication Copaxone, those donations violated the Anti-Kickback Statute ("AKS") and the False Claims Act ("FCA"). The government's theory is fatally flawed for a number of reasons. Accordingly, the Complaint should be dismissed.

The government does not, and cannot, allege that Teva had control of the charities' use of donated funds, much less the right to require the charities to use Teva's donations for Copaxone. On the contrary, the funds to which Teva donated supported a number of MS products, and the charities retained control over the use of those. That ultimate independence over how the funds were dispensed is fatal to the government's case. It "severs the nexus" of Teva's donations under the AKS.

The government also does not allege that any physician was influenced to prescribe Copaxone, or any patient to use it, because of these donations. Indeed, the government fails to identify a single patient who was prescribed Copaxone for any reason other than, in his or her physician's judgment, it was a medically necessary treatment for their MS.

Despite spending considerable time in the Complaint hypothesizing about the potential impact of charitable contributions on drug pricing, the Complaint does not identify a single

---

[1] The Defendants are Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Neuroscience, Inc. ("Teva Neuroscience") (collectively, "Teva" or the "Company").

comparable lower priced treatment, much less a comparable treatment that was not also supported by manufacturer charitable contributions. Instead, the Complaint sets forth the unfortunate but unremarkable proposition that the Medicare Part D structure shifts significant cost burdens onto seniors, many of whom cannot afford much of their medication regimen without help. That pharmaceutical companies assist in addressing this burden in a manner that can also benefit their own products does not convert charitable contributions into criminal acts.

Taken as true for purposes of a motion to dismiss only, the government's factual allegations in this case establish nothing more than that Teva hoped and expected that its charitable donations would help Copaxone patients pay for their medication, and Teva took steps to maximize the chances that would happen. But, that does not create an intent to induce sufficient to establish an anti-kickback violation. If that were the case, no pharmaceutical company could donate to a fund that, even in part, supported its own products without running afoul of the AKS. There has to be something more. To violate the AKS, a donation must be contingent on the charity's agreement to recommend or otherwise promote the donor or its product. There is no such agreement alleged here.

Guidance and opinions from the Department of Health and Human Services Office of Inspector General ("OIG") have consistently reinforced the fundamental proposition that pharmaceutical companies can donate to funds that support their products. And OIG is certainly well aware that for-profit pharmaceutical manufacturers "hope and expect" that their donations will "in whole or in part" support their own products. To conclude otherwise is to engage in a fiction that no court should countenance. Yet, taken to its logical conclusion, the government's theory necessarily converts that hope and expectation into an intent to induce that is violative of the AKS. If the government were correct, then any such donation would violate the AKS

irrespective of the safeguards followed—and the OIG's guidance would be tantamount to counselling in favor of criminality. For that reason, the government cannot satisfy the requisite intent to induce necessary to state a claim.

The Complaint fails to satisfy several other elements of the AKS. Teva's donations did not "induce" or "reward" prescriptions under the AKS. There is no allegation that Teva marketed its donations or otherwise "induced" prescribers or patients in the initial selection of Copaxone as a treatment. The donations that patients received occurred after the prescribing decision and with no attribution to Teva (or any of the other manufactures whose pooled contributions went into the charities). Indeed, the Civil Monetary Penalties Law specifically exempts "remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs." That principle is instructive here. Teva's donations both promote access to care and pose a low risk of harm to Federal health care programs because the donations were made to charities that retained the ultimate discretion in how to distribute their funds.

The government's FCA claim also fails because the government has not identified a single claim that resulted from a Teva donation, which is required to satisfy the statutory causation requirement that a false claim "result from" a violation of the AKS. The Complaint and accompanying exhibits reflect that: 1) other manufacturers contributed to the charities; 2) their pooled donations were not attributed to Teva or marketed to patients or prescribers to influence which medications were selected; and 3) the foundations ultimately disposed of the pooled funds they received from Teva and other manufacturers in the manner they deemed appropriate. The temporal connection between donations and patient funding alleged by the government is insufficient as a matter of law.

The government has failed to state a claim for conspiracy to violate the FCA because it has alleged no facts to show a "meeting of the minds" to defraud the government involving either charity, CDF or TAF. And none of the facts alleged undermine the ultimate independence that the charities ultimately had, and exercised, over the distribution of Teva's (and other manufacturers') donations.

The government's claim for unjust enrichment fails as well. The government's FCA claims confirm it has an adequate legal remedy. Where the government cannot make out the statutory elements under the AKS and the FCA, the Court should not permit it to seek relief beyond what Congress has declared to be unlawful. In any event, the government's unjust enrichment claims fail for the same reasons that its FCA claims fail.

Finally, through this enforcement action, the government chills speech protected by the First Amendment. The government's positon is that what converts a legal donation into a crime is speech and speech alone—the alleged sharing of information relating to donations. However, communications between a donor, like Teva, and a charitable foundation, are unquestionably speech incident to charitable giving. The government's effective restriction on pharmaceutical companies' speech, while not restricting identical speech made by others, runs afoul of the First Amendment and Supreme Court precedent. Under principles of constitutional avoidance, the Court should resolve any doubts in favor of dismissing this action.

At its core, the government's theory conflates donations to charities pooled with other manufacturers to help patients afford their necessary medication, with kickbacks to providers or patients to influence drug choice. This case is an overreach by DOJ, based on a flawed legal theory, and should be dismissed.

II. BACKGROUND

A. Medicare Part D Created the Need for Charitable Assistance.

In 2006, Medicare Part D prescription drug coverage went into effect. The program, however, has a significant shortcoming: it does not subsidize the full cost of prescription drugs. (Compl. ¶¶ 16-21.) Instead, large gaps in coverage remain, leaving seniors with a considerable burden in affording their drugs.

After a Part D beneficiary meets an annual deductible ($250 in 2006), he or she is responsible for a 25 percent co-pay on prescription drugs up until an "initial coverage limit" ($2,250 in 2006). (Compl. ¶¶ 19-20.) Once the "initial coverage limit" is reached, there is a "coverage gap"—also known as the Medicare "donut hole." In that gap, patients are responsible for a high percentage of their brand name prescription drugs (*e.g.*, 100 percent through 2010). (*Id.* ¶ 20.) Medicare beneficiaries must then pay fully out of pocket until an "annual out-of-pocket threshold" is met for the coverage year ($3,600 in 2006). (*Id.* ¶¶ 20-21.)[2] The financial thresholds (*i.e.*, the premiums, annual deductible, initial coverage limit, and out-of-pocket threshold) have increased each year since 2006. (*Id.* ¶ 21.) In 2020, the initial coverage limit is $4,020, the out-of-pocket threshold is $6,350, and an annual deductible can reach $435. 42 C.F.R. § 423.104.[3]

As a result, many retirees cannot afford the medication they need, despite having Medicare Part D coverage. As the Wall Street Journal reported in 2005, people with insurance

---

[2] When in the "donut hole," Medicare beneficiaries were required to pay 100 percent of the costs of brand name prescription drugs from 2006 to 2010, 50 percent in 2011 and 2012, 47.5 percent in 2013 and 2014, and 45 percent in 2015 and 2016. (Compl. ¶ 20.)

[3] *See also Costs for Medicare drug coverage*, Medicare.gov, https://www.medicare.gov/drug-coverage-part-d/costs-for-medicare-drug-coverage.

were finding it increasingly difficult to afford treatment. (Compl. Ex. 7.) This was particularly acute with newer biological medications that "are proteins grown in cells, which is a complex, expensive process" and the companies that developed them took the position that pricing was necessary to "recoup development costs and invest in research." (*Id.*) Indeed, the "biotechnology revolution" had "created hundreds of drugs for chronic, life threatening illnesses." (*Id.*) These drugs are often "a real miracle" for patients suffering from life-altering disorders. (*Id.*) Thus, pharmaceutical company donations to patient assistance charities had begun to provide an important safety net. As one Medicare beneficiary explained to the WSJ: "I feel grateful every day for [the PAP] and the companies that support them." (*Id.*)

In response to the Medicare Part D coverage gap, pharmaceutical companies faced a dilemma. If they stepped in to help patients afford their medication through direct subsidies, they risked incurring the draconian penalties of the AKS and FCA. The solution was to continue the charitable giving that, as the WSJ article cited in the Complaint recognizes, long predated Medicare Part D. (*Id.*)

The federal government, in the form of the OIG, immediately recognized this dilemma as well. It issued the Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees that explicitly recognized the need for continued financial support by industry in the context of Medicare Part D. *See* 70 Fed. Reg. 70623, 70626 (Nov. 22, 2005) ("2005 OIG Guidance"). [4] The OIG acknowledged that "[p]atient assistance programs (PAPs) have long

[4] The Court may take judicial notice of agency guidance. *See, e.g.*, *N. Heel Corp. v. Compo Indus., Inc.*, 851 F.2d 456, 468 (1st Cir. 1988) (taking judicial notice of administrative agency regulations); *Humana Inc. v. Mallinckrodt ARD LLC*, No. CV1906926DSFMRW, 2020 WL 3041309, at *10 (C.D. Cal. Mar. 9, 2020) (taking judicial notice of the 2005 and 2014 OIG Special Advisory Bulletins).

provided important safety net assistance to patients of limited means who do not have insurance coverage for drugs, typically serving patients with chronic illnesses and high drug costs[,]" and that the passage of Medicare Part D did not obviate the need for this "important safety net." *Id.* at 70626. Thus, the OIG observed "that pharmaceutical manufacturers can effectively contribute to the pharmaceutical safety net by making cash donations to independent, bona fide charitable assistance programs." *Id.*

While the OIG's guidance is a policy document and not binding law,[5] the guidance makes clear that, until recently, the government has never taken the position that a donation by a pharmaceutical company to an independent charity with the hope, expectation, or purpose that its donation be used, in whole or part, to support its products violates the AKS. There was and remains no proscription against a manufacturer donating to a fund that supported its own products. 2005 OIG Guidance, 70 Fed. Reg. at 70627. Indeed, even single drug funds (not at issue in this case) were not viewed as necessarily in violation of the AKS. *See id.* n.19. When the 2005 OIG Guidance was updated in 2014, it still did not proscribe donations by companies to funds that supported products including their own. *See* 79 Fed. Reg. 31120 (May 30, 2014) ("2014 OIG Guidance").

Consistent with the 2005 OIG Guidance, in advisory opinions, the OIG repeatedly approved arrangements in which pharmaceutical companies donated to charitable disease state

---

[5] *See, e.g.*, *Jones-McNamara v. Holzer Health Sys.*, 630 F. App'x 394, 400 (6th Cir. 2015); *United States ex rel. Gohil v. Sanofi U.S. Servs. Inc.*, No. CV 02-2964, 2020 WL 4260797, at *8 (E.D. Pa. July 24, 2020).

funds that supported their own products. This included the charities at issue in this case: the Chronic Disease Fund ("CDF") and The Assistance Fund ("TAF"). *See* OIG Adv. Op. No. 06-10 (Sept. 14, 2006) ("CDF Op."), attached as Exhibit 1; OIG Adv. Op. No. 10-07 (May 26, 2010) ("TAF Op."), attached as Exhibit 2.[6] Never once did the OIG find that a donor's subjective intent with regard to the use of its funds to support its own products violated the AKS. That is because the involvement of an independent charity "sever[s] the nexus between the patient subsidies and the manufacturer." 2005 OIG Guidance, 70 Fed. Reg. at 70624 n.3; *accord* CDF Op. 7 ("[CDF] awards assistance in a truly independent manner that severs any link between donors and beneficiaries."); TAF Op. 6 ("[TAF] would award assistance in a truly independent manner that would sever any link between Donors and beneficiaries.").[7]

B. The Alleged Charitable Support

1. Teva's Copaxone Treats Multiple Sclerosis, A Life-Altering Disease.

Among the products that Teva sells is Copaxone. Copaxone is an injectable medicine

---

[6] Subsequently, OIG modified CDF's advisory opinion (Not. of Mod. of OIG Adv. Op. No. 06-10 (Oct. 26, 2015) and TAF's advisory opinion (Nots. of Mod. of OIG Adv. Op. No. 10-07 (May 19, 2011) and (May 5, 2016)). These modified advisory opinions reflected the OIG's continued approval of each charity's patient assistance programs, per the charities' certified information submission.

[7] *See also* CDF Op. n.8 ("This conclusion is consistent with the OIG's November 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees (70 Fed. Reg. 70623; November 22, 2005), in which the OIG made it clear that, in the circumstances described in the Bulletin, cost-sharing subsides provided by bona fide, independent charities unaffiliated with donors should not raise anti-kickback concerns, even if the charities receive charitable contributions from those donors."); TAF Op. n.4 (same). This guidance remained operative during the relevant time period alleged in the Complaint. *See* 2014 OIG Guidance, 79 Fed. Reg. at 31120 ("This Supplemental Special Advisory Bulletin. . . is not intended to replace the 2005 SAB").

used for the treatment of MS. MS is a life-altering disease of the brain and spinal cord that causes often disabling physical symptoms, including problems with mobility, vision, coordination and cognitive function, as well as fatigue and pain.[8] Copaxone is indicated for the treatment of relapsing forms of MS, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.[9] It is given by self-injection under the skin and is generally thought to treat MS through the immune system.[10] While there is no cure for MS, Copaxone and other treatments can slow the progression of MS and decrease the degenerative impact on the patient.[11] Among the drugs used to treat MS are Avonex, Betaseron, Copaxone, Gilenya, Rebif, and Tysabri. (Compl. Exs. 55, 64.) The government does not allege that these drugs were less expensive than Copaxone.

2. Teva's Shared Solutions Program Helps Copaxone Patients Investigate Benefits and Refers Patients to Third-Party Patient Assistance Hubs.

Teva directly assists Copaxone patients through its Shared Solutions program. Shared Solutions is a centralized, patient-focused group offering personalized support to Copaxone

---

[8] *See* https://www.mayoclinic.org/diseases-conditions/multiple-sclerosis/symptoms-causes/syc-20350269. The court may judicially notice a fact that is not subject to reasonable dispute. *See* Fed. R. Evid. 201(b)(2); *Decovich v. Anthem Life Ins. Co.*, 744 F. App'x 466, 467 (9th Cir. 2018) (taking judicial notice under Fed. R. Evid. 201(b) of the fact that "fibromyalgia is characterized by widespread aches and pains" among other characteristics described in the "Mayo Clinic Family Health Book").

[9] FDA Drug Safety Information, Copaxone, https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/020622s110lbl.pdf.

[10] *See* https://www.mayoclinic.org/diseases-conditions/multiple-sclerosis/in-depth/personalized-therapy-for-multiple-sclerosis/art-20095758.

[11] *See* https://www.webmd.com/multiple-sclerosis/qa/can-drugs-that-slow-the-progression-of-multiple-sclerosis-ms-cure-it.

patients. (Compl. ¶¶ 48-49.) Shared Solutions provides patients with educational resources, injection training, proactive outreach by medical practitioners, and benefits investigation services. (*Id.*) A patient may choose to use Shared Solutions to help investigate potential benefits support. (*Id.*)

If Shared Solutions determines that a patient has or is eligible for Medicare Part D coverage, the patient is referred to a third-party patient assistance hub. (*Id.*) These hubs are separate companies that help register a patient for Medicare coverage and/or financial assistance and charitable support. (*Id.* ¶ 50.) From October 2006 to February 2015, the hub with which Teva contracted was Advanced Care Scripts ("ACS"). (*Id.*) From February 2015 through at least the rest of 2015, Teva used AssistRx as the hub. (*Id.* ¶ 52.)

C. The Charitable Foundations, CDF and TAF, Operated Independently of Teva.

The charitable foundations at issue in the Complaint are CDF and TAF. As the OIG concluded in 2006 and 2010, respectively, the structure of CDF's and TAF's patient assistance programs interpose an independent, bona fide charitable organization between donors in a manner that would insulate beneficiary decision-making from information attributing their funding source to any particular donor—*e.g.*, a Copaxone patient would never know that funding came from Teva as a "reward" or to induce goodwill. *See* CDF Op. at 2-4; TAF Op. at 2-4.

In so concluding, the OIG observed, among other things, that CDF and TAF are governed by independent boards of directors. *See* CDF Op. at 2 ("An independent board of directors governs Requestor. The board oversees all policymaking functions for Requestor, such as patient eligibility requirements, categories of diseases addressed, and program requirements for funds established for each disease addressed ("disease funds")); Compl. Ex. 25 ¶ 3(c) ("Program eligibility criteria will be developed by the Board without consideration or input by Donor."). In

addition, CDF and TAF developed objective eligibility criteria without influence and input from donors, the patient's choice of provider, practitioner, insurer, insurance plan, supplier, test, or product. CDF Op. at 3 ("Requestor has established objective criteria for determining grant eligibility that is based on medical condition and financial."); TAF Op. at 3, 4 ("Requestor would not make eligibility determinations based in whole or in part on: the interest of any person or entity who contributes to Requestor's grant program funds ('Donor') or affiliate(s) of Donors; the applicant's choice of provider, practitioner, insurer, insurance plan, supplier, test, or product; or the identity of the referring person or organization (including whether the referring person is a Donor)"; *id*. at 4 "Requestor has certified that no health plan, affiliate of a health plan, Donor, or affiliate of any Donor, would exert any direct or indirect influence or control over Requestor or Requestor's program.").

Moreover, both CDF and TAF processed patient applications on a first-come, first-served basis. CDF Op. at 3; TAF Op. at 3. When funding was available, CDF and TAF awarded grants to eligible patients regardless of the MS medication they had been prescribed. This helped to ensure that needy patients were not deprived of their medically necessary medications. (Compl. ¶ 64; Compl. Ex. 25 ¶ 5(b); Compl. Ex. 26 ¶ 19 at Tev_167548.) This was in furtherance of the charities' explicit mission to "strive[] to fully help Medicare Part D patients with their co-payment responsibilities during initial coverage, the coverage gap and with catastrophic coverage." (*Id*. Ex. 26 ¶ 14 at Tev_167547.)[12]

[12] *See also* https://tafcares.org/donors/how-we-help-2/ ("We help patients facing high medical out-of-pocket costs by providing financial assistance for their co-payments, coinsurance, deductibles, and other health-related expenses.").

Teva therefore understood that, per the terms of its donation agreements with each charitable foundation, Copaxone was one of many MS drugs covered by donations received. (*See, e.g.*, Compl. Exs. 25, 55, 64.) Teva's donations were used to support non-Copaxone patients and other donor's donations covered Copaxone patients, (*id*. Ex. 2 ¶ 9), and Teva was aware of that and continued to make donations. (*Id*. Ex. 45.)

For example, CDF had established "an assistance program for patients being treated for Multiple Sclerosis with any medically appropriate therapy who meet certain financial and medical criteria ("*Program*"). (*Id*. Ex. 25 ¶ 1) The CDF Program Donation Agreement for MS provided: "Donor will have no control or participation in determinations affecting distributions of Program funds to providers, suppliers, or patients, or the products or treatments provided to treat or in connection with multiple sclerosis." (*Id*. ¶ 3(c)) Further, in a section entitled "**Independence of the Foundation and Program**," the CDF Agreement made clear that CDF's Board "will have complete authority regarding the distribution of all Program funds (including the Donation)." (*Id*. ¶ 3(a).)

From 2006 to 2014, Teva donated money to CDF's MS fund. (Compl. Ex. 1.) From 2009 to 2015, Teva donated money to TAF's MS fund. (*Id*.) Despite accusing Teva of violating the AKS, the government acknowledges that Teva's donations were both medically and financially necessary. (*Id*. Ex. 2 ¶ 19) (Teva's donations and the work of ACS, CDF, and TAF, "benefit[ed] patients with medically necessary MS prescriptions and legitimate financial need."). Furthermore, as the Affidavit the government attached to the Complaint concedes, it may be that not all of the money that Teva donated was used to support Copaxone patients. Instead, at least some of those funds may have used for "**non-Copaxone patients** who were in dire need of co-pay assistance." (*Id*. ¶ 9) (emphasis added).

III. LEGAL STANDARD

A court must dismiss a complaint under Rule 12(b)(6) when plaintiff "fail[s] to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). To plead a viable cause of action, the allegations must transcend the "speculative," "conceivable," and "possible," and must "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 556-57, 566-67, 570 (2007). "Plausible . . . means something more than merely possible, and gauging a pleaded situation's plausibility is a context-specific job that compels [the court] to draw on [its] judicial experience and common sense." *Lyman v. Baker*, 954 F.3d 351, 360 (1st Cir. 2020). In ruling on a motion to dismiss under Rule 12(b)(6), a court must disregard "legal conclusions" and "conclusory" allegations, and must scrutinize the well-pled allegations to ensure that they are more than "'merely consistent with' a defendant's liability." *Ashcroft v. Iqbal*, 556 U.S. 662, 677–79 (2009).

"In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). For claims based on the FCA, Rule 9(b) "requires both that the circumstances of the alleged fraud and the claims themselves be alleged with particularity." *Lawton ex rel. United States v. Takeda Pharm. Co., Ltd.*, 842 F.3d 125, 130 (1st Cir. 2016).

The government alleges that Teva violated the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, by violating the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a–7b.[13] The

[13] The government alleges that Teva violated: 31 U.S.C. § 3729(a)(1)(A) (2009), formerly 31 U.S.C. § 3729(a)(1) (Compl. ¶¶ 121-124); 31 U.S.C. § 3729(a)(1)(B) (2009), formerly 31 U.S.C. § 3729(a)(2) (Compl. ¶¶ 125-128); and 31 U.S.C. § 3729(a)(1)(C) (2009), formerly 31 U.S.C. § 3729(a)(3) (Compl. ¶¶ 129-132).

FCA's presentment clause, 31 U.S.C. § 3729(a)(1)(A), is violated when any person presents, or causes to be presented, "false or fraudulent claim[s] for payment or approval" to the federal government. *Hagerty ex rel. United States v. Cyberonics, Inc.*, 844 F.3d 26, 31 (1st Cir. 2016). The FCA's false records clause, 31 U.S.C. § 3729(a)(1)(B), is violated when any person "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *United States ex rel. D'Agostino v. EV3, Inc.*, 153 F. Supp. 3d 519, 530 (D. Mass. 2015), *aff'd sub nom. D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016). The FCA's conspiracy clause, 31 U.S.C. § 3729(a)(1)(C), is violated when any person conspires to commit a violation of the FCA. *Id.* "Because FCA liability attaches only to false claims, merely alleging facts related to a defendant's alleged misconduct is not enough. Rather, a complaint based on [the FCA] must sufficiently establish that false claims were submitted for government payment as a result of the defendant's alleged misconduct." *United States ex rel. Ge v. Takeda Pharm. Co.*, 737 F.3d 116, 124 (1st Cir. 2013).

The AKS prohibits individuals or entities, *inter alia,* from knowingly and willfully paying "remuneration" in order to induce or reward the referral of business reimbursable under Federal health care programs, including Medicare. *See* 42 U.S.C. § 1320a-7b(b)(2)(B). Illegal remunerations include any "kickback, bribe, or rebate" provided or sought "directly or indirectly, overtly or covertly, in cash or in kind." *Lawton ex rel. United States v. Takeda Pharm. Co., Ltd.*, 842 F.3d 125, 128 n.4 (1st Cir. 2016); *Guilfoile v. Shields*, 913 F.3d 178, 188-89 (1st Cir. 2019) ("the AKS prohibits "remuneration . . . to induce a person to 'recommend . . . ordering any . . . service . . . for which payment may be made in whole or in part under a [f]ederal health care program"); *see also id.* at 190 (based on the statutory "resulting from" language, a claim is "false within the meaning of the FCA" provided "there is a sufficient causal connection between an

AKS violation and a claim submitted to the federal government").

IV. ARGUMENT

A. The Government Fails to Allege a Violation of the Anti-Kickback Statute.

1. The Government Fails to Allege That Teva Had the Requisite Intent to Induce or Reward Medicare Purchases.

The government's AKS claim fails because Teva's alleged hope and expectation that its donations be used for Copaxone is insufficient to show an intent to induce or reward business under the AKS. *See United States ex rel. Ruscher v. Omnicare, Inc.*, 663 F. App'x 368, 374 (5th Cir. 2016) (*citing United States v. McClatchey*, 217 F.3d 823, 834 (10th Cir. 2000) ("There is no AKS violation . . . where the defendant merely hopes or expects referrals from benefits that were designed wholly for other purposes."). As explained by the U.S. Court of Appeals for the Tenth Circuit in *McClatchey*, a company "may lawfully enter into a business relationship" and "even hope for or expect referrals" without violating the AKS. *McClatchey*, 217 F.3d at 834. In short, there has to be something more than mere "hope and expectations" of a benefit in order to show an intent to induce violate the AKS. *See id.*[14]

a. The Government Must Allege Facts That Plausibly Show that Teva Controlled the Charities' Use of Their Funds.

[14] The contrast between the AKS and closely related Beneficiary Inducement Statute ("BIS"), 42 U.S.C. § 1320a-7a(a)(5) is instructive here. The BIS, which defines only a civil penalty, prohibits "remuneration" to a federal health insurance beneficiary that the payer "knows or should know is likely to influence" the beneficiary to select a particular provider, practitioner, or supplier. *Id.* By reaching payments that are "likely to influence," the BIS prohibits foreseeable influence on the selection of providers, and thus sweeps more broadly than the AKS, which prohibits kickbacks that are intended "to induce." 42 U.S.C. § 1320a-7b(b)(2). The textual differences in these statutes reflect that Congress intended the AKS to have a different and narrower construction than the BIS. Yet, here, the government tries to import the BIS' foreseeability standard into the AKS, rather than applying the AKS' stricter intent-to-induce requirement.

The "something more" that is required under the AKS with regard to charitable contributions is not the receipt of information from a charity that helps a donor anticipate the charitable need for its products. Instead, it is a donor's control over a charity's disposition of the funds. It is this control that creates the necessary nexus between the donation and recipient that converts the charity into a conduit for the inducement of referrals.

Thus, a drug manufacturer "***cannot be liable*** for giving money to co-pay foundations" absent evidence "that these donations were ***contingent*** on the foundation's ***agreement*** to purchase or recommend [the manufacturer's] drugs." *See United States v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1057 (C.D. Cal. 2016) (emphasis added). In *Celgene*, the court granted summary judgment to Celgene, the manufacturer donor, where "Celgene gave tens of millions of dollars per year to non-profit organizations for the purpose of helping patients (including those enrolled in Medicare) pay for ten different drugs treating the disease state including three of which were manufactured by Celgene." *Id.* This was because there was no evidence that the donations were "contingent on the foundation's agreement" to benefit Celgene. The court concluded that "[a]bsent evidence of this sort, Celgene cannot be liable for giving money to co-pay foundations." *Id.*

The *Celgene* court's requirement of an explicit agreement requiring the charity to use the donation for the benefit of the donor is a proper reading of the outer limits of the AKS's application to charitable giving. The court in *Celgene* found no such agreement where CDF—one of the foundations at issue in this litigation—reimbursed ten different multiple myeloma drugs, only three of which were manufactured by Celgene. *Id.* at 1057 n. 33. Without the limitation that donations were "contingent on the foundation's agreement," the AKS could reach all charitable giving where the manufacturer donates to an independent disease fund with the

hope and expectation of benefitting the users of its medications. But that is not the law. *See McClatchey*, 217 F.3d at 834.

The government's attempt to distinguish *Celgene* in the *United States v. Regeneron* action, No. 20-cv-11217 (D. Mass) (Saylor, C.J.), which is pending in this District and raises similar issues and claims, is unavailing. In that litigation, the government noted that it "respectfully disagrees" with *Celgene* and argued that the "relevant question is whether the manufacturer knew that the foundation would use its money on the manufacturer's drugs[.]" *United States v. Regeneron*, No. 20-cv-11217, Gov't Opp'n to Mot. to Dismiss (ECF No. 24) at 18-19 n.4. The government's position, however, would criminalize virtually all patient assistance programs. Indeed, during a recent oral argument on a motion to dismiss in *United States v. Regeneron*, counsel for the government suggested a virtually unbounded limitation on AKS liability in the context of charitable giving. *See id.*, Oct. 7, 2020 Tr. at 55:5-17 ("The Court: "Suppose … you give 25 million knowing that some substantial portion of that is going to wind up with Lucentis [product manufactured by Regeneron competitor] patients?" Mr. Shapiro: "That would also be problematic if you know that the money is going to your patients."). But that position is inconsistent with *McClatchey* and, *Celgene*.

It is also flatly inconsistent with the OIG's repeated recognition that a pharmaceutical manufacturer's support of charitable funds that support its own product does not violate the AKS. That guidance makes clear that a manufacturer does not violate the AKS even where it necessarily would both desire and expect that its contributions would benefit the consumers of its product. Instead, as the OIG has recognized, the interposition of an independent charity provides "sufficient insulation so that the [charity's] assistance to patients should not be attributed to any of its Donors." CDF Op. at 8; TAF Op. at 8. The charity's independence "sever[s] the nexus

between the patient subsidies and the manufacturer." 2005 OIG Guidance, 70 Fed. Reg. at 70624 n.3; (Compl. Ex. 25 ¶ 5(b).). While OIG guidance adds additional prophylactic factors to "reduce[] risk" that are untethered to the contingent use limitation required by the AKS, those requirements are not the law.[15] The *Celgene* court therefore properly held that to violate the law, there must be a contingent agreement to use the donor's donation to support the donor's product. *See Celgene*, 226 F. Supp. 3d at 1057.

This case stands in sharp contrast to the factual allegations found sufficient in *United States el rel. Strunck v. Mallinckrodt Ard LLC*, No. 12-175, 2020 U.S. Dist. LEXIS 10191 (E.D. Pa. Jan. 21, 2020)[16]. In that case, the government alleged that the manufacturer had control over the charity. *See id*. at *21. In particular, the manufacturer "designed, created" and "exerted control over the various funds it set up through CDF." *Id*. at *2 & *21. This control was shown by the fact that the manufacturer and charity created separate funds for patients who were only treated with the manufacturer's product, as opposed to the disease state funds involving support for multiple products at issue in this litigation. *See id*. ("Specifically, [the government] alleges that Mallinckrodt insisted on establishing new, separate 'exacerbation' funds for each funded disease in order to ensure that only patients treating with Acthar would receive the benefits of its 'donations.'"). As a result, in *Mallinckrodt*, the manufacturer "exerted control of the various

---

[15] Indeed, the 2005 and 2015 OIG Guidance even allow for the possibility of lawful arrangement in which a single-drug foundation would support only the donor's product. 70 Fed. Reg. at 70627 n.19; *see also* 2014 OIG Guidance, 79 Fed. Reg. at 31122 (noting the potential for a "disease fund that covers only a single product, or the products made or marketed by only a single manufacturer that is a major donor to the fund").

[16] Mallinckrodt recently declared bankruptcy and has moved to stay proceedings in that litigation. *See* No. 12-175 (ECF No. 98) (E.D. Pa. Oct. 13, 2020).

funds it set up . . . ." *Id.* at *6. It is that "control" that creates the type of arrangement that the Court in *Celgene* suggested could be unlawful under the AKS. *See Celgene*, 226 F. Supp. 3d at 1057.

b. The Government's Factual Allegations Demonstrate that Teva Did Not Have Control Over The Charities.

The government has not alleged facts that plausibly show a contingent agreement controlling between Teva's donations and CDF's and TAF's support to patients as was alleged in *United States v. Mallinckrodt*. The Complaint here does not allege that CDF or TAF agreed with Teva to use its donations to support Copaxone. Instead, as in *Celgene*, the "evidence suggests the opposite." *Celgene*, 226 F. Supp. 3d at 1057. The MS funds supported patients being treated with at least five MS treatments other than Copaxone, (Compl. Exs. 55, 64), and one of the Complaint's exhibits explicitly posits that at least some of Teva donations to CDF may have been used to support non-Copaxone patients. (Compl. Ex. 2 ¶ 9.) Nor does the Complaint contain any allegations that any Teva employee instructed that Teva donations be directed solely to Copaxone patients, or threatened to withhold donations if they were not directed to Copaxone patients. To the contrary—Teva was aware that donations were being used to support other manufacturer-donor's products as early as 2009, and it nevertheless continued to make contributions thereafter. (Compl. Ex. 45.)[17]

[17] The only e-mail the government cites stating that "particular manufacturer funds go to their own drug" does not involve Teva, and does not attribute that direction or intent to Teva. (Compl. Ex. 8.) To the contrary, this internal ACS e-mail pertains to both Copaxone and a competing MS treatment, Avonex,

CDF's Donation Agreement with Teva further evidences the charity's independence, which "sever[s] the nexus between the patient subsidies and [Teva]." 2005 OIG Guidance, 70 Fed. Reg. at 70624 n.3; (Compl. Ex. 25 ¶ 5(b).) ("[CDF] shall not preferentially treat or discriminate against a patient whose treatment is manufactured or marketed by Donor or upon any physician or supplier utilized by such patient.").[18] OIG itself observed other evidence of independence, including: 1) that CDF and TAF are governed by independent boards of directors; 2) CDF and TAF developed objective eligibility criteria without influence and input from donors, or the patient's choice of provider, practitioner, insurer, insurance plan, supplier, test, or product; and 3) both CDF and TAF processed patient applications on a first-come, first-served basis. (*See* Exs. 1, 2.)

That Teva may have taken steps to increase the chances that its hopes and expectations that its donations would support Copaxone would come to fruition in no way undercuts the fundamental independence of these charities. Similarly, the government's allegations that a former TAF employee "understood" that Teva structured its donations in such a way that purportedly ensured that they would benefit Copaxone patients, (Compl. Ex. 2 ¶ 3), or that Copaxone patients were enrolled near in time to Teva's donations through so-called "batch

---

and reflects that: 1) CDF supported, at a minimum, both Copaxone and Avonex patients; and 2) Teva and Biogen (Avonex's manufacturer) made contributions to the fund. *See id.*

[18] A Court may consider the full text of documents that are quoted in or attached to the complaint on a motion to dismiss. *See, e.g.*, *Bank of New York Mellon Tr. Co. v. Morgan Stanley Mortg. Capital, Inc.*, No. 11 Civ. 0505, 2011 WL 2610661, at *3 (S.D.N.Y. June 27, 2011) ("In deciding a motion to dismiss, this Court may consider the full text of documents that are quoted in or attached to the complaint . . . .").

files," (Compl. ¶¶ 77, 90),[19] do not alter the undisputed fact that Teva's donations were part of a pool of donations that benefited MS patients being treated with Copaxone and other medications. (*id*. Ex. 2 ¶ 9). There was no contingent agreement that Teva's donations be used to support Copaxone. *See Celgene*, 226 F. Supp. 3d at 1057.

Thus, even under the government's own near-limitless reading of the AKS's application to charitable giving, it has not plead that Teva had the requisite intent or inducement. The charities retained the right to use Teva's donations to support other products. And the exhibits to the Complaint show that Teva knew that a manufacturer's donation to the MS funds could and indeed were used to support another manufacturer's MS product.

c. The Government's Reliance On Teva's Alleged Usage of Data Is Unavailing and Is Inconsistent With DOJ Policy.

Absent any alleged agreement between Teva and the charities, the government relies on its "three data points" theory, which rests solely on the OIG's suggested prophylactic factors, and

[19] The government alleges that Teva received so-called "period reports" from ACS that allowed Teva to ensure that the "vast majority" of Teva's payments to the foundations went to cover Medicare co-pays of Copaxone patients. (Compl. ¶ 5.) This implicates the OIG "safeguard" that the foundation not provide information that allows the donor to correlate its donations. But the "safeguards" are just that – they are prophylactic and intended to "reduce[] risk"—they are not dispositive of what constitutes an AKS violation. Even accepting the government's allegation as true for purposes of this motion only that the data allowed Teva to correlate the size and timing of its donations to maximize the donations utilization by Copaxone patients, Compl. ¶¶ 79–100, there is nothing in the AKS—or any other law—that prohibits such conduct, and the OIG's guidance regarding single-drug funds makes clear that knowledge and understanding that donations would benefit a specific population is not sufficient to create liability under the AKS. Such allegations therefore fall short of the "control" required. *See, e.g.*, *Mallinckrodt Ard LLC*, 2020 U.S. Dist. LEXIS 10191, at *21.

not the AKS itself.[20] However, the OIG's prophylactic factors are not legal requirements. *See, e.g., Jones-McNamara v. Holzer Health Sys.*, 630 F. App'x 394, 400 (6th Cir. 2015); *United States ex rel. Gohil v. Sanofi U.S. Servs. Inc.*, No. CV 02-2964, 2020 WL 4260797, at *8 (E.D. Pa. July 24, 2020); *see also United States v. Regeneron*, No. 20-cv-11217, Oct. 7, 2020 Tr. at 52:13-15 (Government: "The data sharing, which is although in violation we would argue of the OIG guidance is not in itself an element of the anti-kickback statute.").

The government contends that Teva used three pieces of information to calculate how much to donate to CDF and TAF to ensure that their MS funds would cover Copaxone patients the following year. However, this does nothing to undercut the fundamental fact that the allegations make plain the charities, not Teva, controlled how Teva's donations would be used.

In any event, these receipt of this information by Teva, does not in any way undercut the independence of the charities. Two of the data points were publicly available or otherwise readily ascertainable, and the third was not provided directly by the funds, but instead through and by ACS. The government alleges that Teva needed: (1) the fund's annual per-patient grant amount; and (2) the annual per-patient grant amount was simply the Medicare Part D coverage gap, and the Complaint itself sets forth the components and respective amounts of that gap, which is a public matter of record and "easily determinable." (Compl. ¶¶ 19-23; Compl. Ex. 2 ¶

[20] The 2005 OIG Guidance recognized that there may be circumstances where "the fact that a disease category only includes one drug or manufacturer would not, standing alone, be determinative of an anti-kickback statute violation." *Id.* at 70627 n.19. In such a case, the manufacturer would necessarily know and intend that its contributions would benefit only the consumers of its product. *See id.* But the intent and purpose that matters for the AKS under the OIG's guidance is different: it is the purposeful intent to "induce" or "reward" Medicare purchases. *See id.* at 70625 ("Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated.").

6; *see also* "Costs in the coverage gap," *available at* https://www.medicare.gov/drug-coverage-part-d/costs-for-medicare-drug-coverage/costs-in-the-coverage-gap.) And Teva's internal documents attached to the Complaint demonstrate that it used that already publicly available information to calculate those out-of-pocket costs. (Compl. ¶ 24; Compl. Ex. 5.) As to the administrative fee, charitable donors are entitled to know what portion of their contributions will be used for charity as opposed to administration. Thus, the administrative fee was included in CDF's materials distributed to all donors, and was otherwise publicly available on TAF's website. (Compl. Ex. 26.) Indeed, transparency in the disposition of donations is fundamental to charitable giving. [21]

The third "data point" was the number of Copaxone patients enrolled in each fund. However, CDF and TAF "were generally reluctant to provide Teva with precise data on the number of Copaxone patients they were assisting," (Compl. ¶ 78) and never provided that information directly to Teva. Nor is there any allegation that the charities—or anyone at the charities—provided Teva with the total patients in the fund, or the percentage of Copaxone patients in the fund. (*Id.* ¶ 71.) Instead, the allegations are that Teva obtained the number of Copaxone patients in the funds via ACS and the number eligible for patient assistance from ACS. (Compl. ¶¶ 78, 82, 86.) ACS was a third party hub contracted by Teva. The government does not allege that CDF or TAF operated ACS' agents, or vice versa. *See id.* CDF/TAF's sharing of the number of Copaxone patients in the funds to ACS does not reflect its lack of

[21] Thus, Section 501(c)(3) tax exempt charitable organizations that are required to make public their IRS returns (26 U.S.C. § 6104; 26 C.F.R. § 301.6104(d)-1) including, among other things, "gross income, receipts, and disbursements." *See* 26 U.S.C. § 6033(a)(1). *See* https://tafcares.org/donors/how-are-donations-used.

independence from Teva because CDF and TAF retained ultimately discretion with how to use Teva's and other manufacturer's funds. At most, taking the allegations as true, CDF and TAF did not adhere to one of OIG's prophylactic factors. That does not amount to an AKS violation by Teva.

The government's overreach here is further demonstrated by its inconsistent application of Department of Justice ("DOJ") policy. The DOJ recognizes that regulatory guidance cannot establish a violation of law. *See* DOJ Justice Manual § 1-20.100 (actions "must be based on violations of applicable legal requirements, not mere compliance with guidance documents issued by federal agencies, because guidance documents cannot by themselves create binding requirements that do not already exist by statute or regulation."); *see also* Memorandum from Rachel Brand, Assoc. Att'y Gen., U.S. Dep't of Justice to Heads of Civil Litigating Components U.S. Att'ys, Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases (Jan. 25, 2018) (hereinafter the "Brand Memo") (noting that the DOJ "may not use its enforcement authority to effectively convert agency guidance documents into binding rules," and that DOJ litigators "may not use noncompliance with guidance documents as a basis for proving violations of applicable law . . . ."). The government's effort here to transform alleged non-compliance with the prophylactic factors in the OIG's guidance into a violation of the law should be rejected.

Finally, the government's cursory attempt to equate an "intent to make money," (Compl. ¶ 57), with an "intent to induce" should be rejected. At bottom, that Teva was aware that its charitable donations to an MS fund would support the purchase of Copaxone prescriptions (and thus received an internal "Copaxone donations" label) is a matter of logic and the publicly known deficiencies of the Medicare Part D system do not equate intent to defraud. (Compl. Ex.

7.) The very purpose of the charitable foundations was to provide financial assistance to patients suffering from MS. (*See e.g.*, *id*.) And as the government itself alleges, there is a significant population of MS Medicare Part D patients who simply do not have enough money to pay for their MS treatments (Copaxone or otherwise), and can only do so with the support of patient assistance programs like CDF and TAF. (*Id.*) To do so would ensure that manufacturers are no longer able to support patient assistance programs.

2. The Government Fails to Allege That Teva Improperly Induced Doctors or Patients to Use Copaxone.

There are no facts alleged to support the conclusion that Teva's donations influenced any physician to prescribe or patient to purchase Copaxone. The government alleges no facts support such an inference of inducement—let alone with the particularity required under Federal Rule of Civil Procedure 9(b). The AKS prohibits "the use of payments to improperly influence decisions on the provision of health care that lead to claims for payment to federal health care programs." *Guilfoile v. Shields*, 913 F.3d 178, 192–93 (1st Cir. 2019); *see also United States v. Krikheli*, 461 F. App'x 7, 11 (2d Cir. 2012) (the item of value must be offered with the intent that it serve "as a quid pro quo in return for" the referral or purchase, and thereby "to gain influence over the reason or judgment" of the party receiving the remuneration); *United States v. Medtronic*, 189 F. Supp. 3d 259, 268, 271 (D. Mass. 2016); *Hanlester Network v. Shalala*, 51 F.3d 1390, 1398 (9th Cir. 1995) ("[T]he phrase 'to induce' in § 1128B(b)(2) of the [AKS] connotes 'an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business.'").

Nor does the government allege that Teva marketed its charitable donations as a means to influence a doctor's or a patient's decision regarding what medication initially to select or

whether to continue using Copaxone. *Compare Mallinckrodt Ard LLC*, 2020 U.S. Dist. LEXIS 10191, at *14 (noting that the product was "market[ed] as free to doctors and patients" which the sales representatives cited as "one of the most important tools they used to get doctors to prescribe" the product); *United States ex rel. Emerson Park v. Legacy Heart Care, LLC*, No. 3:16-CV-0803-S, 2019 WL 4450371, at *12 (N.D. Tex. Sept. 17, 2019) (N.D. Texas 2019) (dismissing FCA claim where the complaint did not "plead facts showing that any patient agreed to receive treatment because of a co-pay waiver or reimbursement of transportation expenses" and therefore "did not sufficiently plead that any patient was actually induced . . . .").

As the Complaint makes plain, it is only after the prescribing and purchase decision is made that the co-pay becomes due, and the support is needed. "***[A]fter*** a physician writes a prescription for a Medicare Part D beneficiary, the patient can take the prescription to a pharmacy or submit it to a mail order specialty to be filled. When the patient submits the prescription, the Medicare co-pay is due from the patient to complete the purchase of the drug and have the pharmacy fill the prescription." (Compl. ¶¶ 26-27 (emphasis added).) Thus, a prescriber and patient's collective decision about what MS treatment to use occurs long before any charitable donations enter the picture, and is made without Teva's involvement. A physician's decision to prescribe Copaxone—and his or her patient's decision to purchase it—occur in the physician's office. Absent from the Complaint is any allegation that Teva corruptly influenced any prescriber or patient.

The government will likely argue, as it does in the *Regeneron* action, that the AKS does not require that it plead a "corruption of judgment" that influences clinical decision-making.

United States v. Regeneron, No. 1:20-cv-11217-FDS, ECF No. 24, at 30.[22] But under the government's theory, the decision-makers (here, physicians and patients), need not even be aware of the alleged kickback. That is not supported by case law. The case law reflects that the decision-maker needs to be aware of the existence of the kickback at the time of the prescribing or purchasing decision. In *United States ex rel. Vitale v. MiMedx Group, Inc.,* 381 F. Supp. 3d 647 (D.S.C. 2019), the court denied a motion to dismiss where relator alleged that MiMedx directly "consult[ed]" with "patients, clinic staff responsible for treating patients, and billing staff tasked with processing paperwork to obtain payment," and were thus aware of the source of the funding and identity of the donor. *See* No. 3:17-cv-00166-RBH, ECF No. 1, ¶¶ 64, 118, 138-142 (D.S.C.). In *United States ex rel. Brown v. Pfizer, Inc.*, No. CV 05-6795, 2017 WL 1344365, at *7 (E.D. Pa. Apr. 12, 2017), the court likewise denied a motion to dismiss where relators described Pfizer's alleged "establish[ment of] a program 'created to reward doctors who are willing to do whatever it takes to write Vfend.'" *Brown*, 2017 WL 1344365, at *7. The complaint described various tactics—such as extravagant meals, travel, and gifts—that Pfizer's sales representatives purportedly utilized to "encourage" and "convince" physicians to prescribe Pfizer's drug. *Id*. Absent such allegations, dismissal is warranted. *See, e.g.*, *United States ex rel. Osheroff v. Tenet Healthcare Corp.*, No. 09-22253-CIV, 2012 WL 2871264, at *8 (S.D. Fla. July 12, 2012) (dismissing complaint where there were no allegations of how physicians were

[22] The government cites *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F. 3d 89, 96 (3d Cir. 2011) for the proposition. But *Greenfield*, which was analyzing what was needed to prove causation under the FCA, not intent to induce under the AKS, does not hold that a corruption of the decision-maker is not required. Rather, it held that, to prove causation, "something less than proof that the underlying medical care would not have been provided but for a kickback" is needed. *Id.* We address *Greenfield* and the government's failure to plead causation under the FCA *infra* at IV.B.

induced, including no allegations "that any particular physicians were induced to alter their referral decisions on account of their financial relationship with the Defendants"). Here, there is a complete absence of allegations concerning how Teva induced physicians to prescribe or patients to fill Copaxone prescriptions.

3. The Government Fails to Allege That Teva Improperly Rewarded Patients for Using Copaxone.

Nor do the allegations in the Complaint support any theory that the donations were intended to influence patients' choice of medication or induce patients to purchase Copaxone. Here, the government has not pled facts that suggest the existence of any lower cost substitutes for Copaxone at the relevant time that a Medicare beneficiary would have switched to in the absence of Teva's charitable donations (or any alternatives that were not supported by charitable donations). *C.f. United States v. Mallinckrodt Ard LLC*, No. 12-175, 2020 U.S. Dist. LEXIS 10191, at *6 (E.D. Pa. Jan. 21, 2020) (accepting government's theory for purposes of motion to dismiss in part where complaint alleged "there were many low-cost alternatives available").[23] In the *Regeneron* action, the government alleges that doctors would have prescribed a lower cost alternative but for the charitable donations of the manufacturer.[24] The same is true in the *United*

[23] Nor has the government alleged anything other than speculation that the market price for Copaxone would have been lower in the absence of any charitable donations. (*E.g.*, Compl. ¶ 7.) What's more, the government's assertion that unstated "market forces" would lead to lower prices based on "consumer sensitivity and competition" (*id.* ¶ 25) does not withstand scrutiny in this context. The government fails to acknowledge that even if it had alleged the existence of a lower-priced alternative for Copaxone, and it has not, a patient still may not be sensitive to price changes (either up or down) where the beneficiary reaches the out-of-pocket maximum. This is because any price changes above the out-of-pocket maximum would only be passed on to a Medicare beneficiary in the form of a fractional 5% co-pay. *See id.* ¶ 24 (illustrating co-pay structure).

[24] *United States v. Regeneron*, No. 20-cv-11217 (ECF No. 1) (D. Mass).

States ex rel. Vitale v. MiMedx Group, Inc. *See* No. 3:17-cv-00166-RBH, ECF No. 1, ¶ 67 (D.S.C.) ("MiMedx reps argued to program directors and private physicians that the use of its products—far more expensive than most wound care products—would generate profits for the customer, which charge for the sale and application (i.e., grafting) of MiMedx products at a higher rate than for the use of standard of care products."). Here, however, the government alleges no such lower priced alternatives.

We anticipate that the government will rely upon *United States ex rel. Goodman v. Arriva Med., LLC*, No. 3:13-CV-0760, 2020 WL 3840446, at *2 (M.D. Tenn. July 8, 2020) for the proposition that co-pay subsidies necessarily influence treatment decisions. But in *Arriva Medical*, the defendant allegedly waived the co-pay for diabetic testing strips and glucose meters at the time of purchase, thus influencing and rewarding the patients' vendor choice among fungible alternatives. *Id*. The court explained that that factual pattern, involving fungible medical products, is reflective of the typical case involving enticements to choose one provider over another. *Id*.

Moreover, as discussed above, the structure of TAF's and CDF's organization and their MS funds further eliminate the possibility that Teva improperly rewarded patients for using Copaxone. Both TAF and CDF are governed by independent bodies that developed eligibility criteria without input from donors. *See* Exs. 1, 2. To the contrary, the foundations agreed "not discriminate against or otherwise vary its procedures for processing a patient who applies to the Program based upon the treatment prescribed for such patient," and awarded co-pay assistance to patients on a first-come, first-served basis. (Compl. Ex. 2 ¶¶ 5, 10; *see also* Compl. Ex. 25 ¶ 5(b).) Thus, the donations could not have impacted the patients' choice of medication. Furthermore, no patients were informed of the source of their donations. Ex. 1, CDF Op. at 9;

Ex. 2, TAF Op. at 9.

Indeed, funding which promotes access to care – rather than influencing prescriber or patient choice – falls outside of the scope of conduct which the law seeks to proscribe. Thus, prohibited "remuneration" within the meaning of the civil monetary penalty provisions of the AKS, specifically exempts "remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs." 42 U.S.C. §1320a-7a(i)(6)(F).

Here, Teva's charitable donations "promote[d] access to care" because they made critical MS medication available to Medicare beneficiaries with financial need. (*See* Compl. Ex. 2, at ¶ 19.) Moreover, it is clear from the OIG's advisory opinions addressing the two charities at issue that there was a "low risk of harm" because: the foundations' had independent boards unaffiliated with donors; the foundations independently developed objective eligibility criteria developed without influence of donors; Teva's donations were pooled with other manufacturers' donations; and the MS funds had ultimate control over the disposition of the funds. CDF Op. at 7; TAF Op. at 6. The OIG also specifically observed that, with regard to both CDF and TAF's patient assistance programs: "Before applying for assistance, each patient will have already selected his or her health care providers, practitioners, suppliers, and products and will already have a treatment regimen in place. All patients remain free, while receiving [CDF's/TAF's] assistance, to change their health care providers, practitioners, suppliers, or [products]. . . . [CDF/TAF would] not refer any patient to any [donor or affiliate] or to any provider, practitioner, supplier, or [product]." CDF Op. at 7; TAF Op. at 6.

B. The Government Fails to Allege a Violation of the False Claims Act.

The Complaint should be dismissed for the additional reason that the government has not pled a violation of the FCA. Under the FCA, a false claim must "result[] from" a violation of the

AKS. 42 U.S.C. § 1320a-7b(g). "Resulting from" has been interpreted to mean a "sufficient causal connection" between the AKS violation and the submission of any false claim. *Guilfoile*, 913 F. 3d at 190; *see also United States ex rel. Booker v. Pfizer, Inc.,* 847 F.3d 52, 57 (1st Cir. 2017) ("FCA liability attaches only if [fraudulent] conduct resulted in the filing of a false claim for payment from the government.").

The Complaint, however, does not sufficiently link the Teva-specific donations (the alleged kickbacks) to reimbursement claims (the allegedly false claims) to satisfy the "resulting from" requirement because: 1) other manufacturers contributed to the foundations; 2) the pooled donations were not attributed to Teva or marketed to patients or prescribers to influence what medications were selected and used; and 3) the foundations ultimately disposed of the donations they received from Teva and other manufacturers in the manner they deemed appropriate. (*See* Compl. Exs. 2 ¶ 9, Ex. 8, Ex. 45.)

In *Greenfield*, which was cited with approval by the First Circuit in *Guilfoile*, the Third Circuit, rejected the argument that "the taint of a kickback "renders every reimbursement claim false." 880 F. 3d at 100. Instead, the government must plead that "a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient." *Id.* Thus, mere "temporal proximity between [the] alleged kickback plot and the submission of claims for reimbursement," is insufficient to show causation. *Id*.[25] That is because temporal proximity alone does not "rule out the chance" that

[25] While *Greenfield* affirmed summary judgment, the import for the pleadings stage is clear. It is not enough under Rule 9(b) or the FCA statute to allege a temporal proximity between Teva's donations and

patients who submitted the allegedly false claims were not "exposed to an illegal referral or recommendation." *Id.* at 99–100.

In contrast to a garden-variety tort or employment claim in which such temporal inferences may be sufficient at the pleading stage, the FCA requires pleading fraud consistent Federal Rule of Civil Procedure 9(b). As explained by the U.S. Court of Appeals for the Eleventh Circuit in *United States ex rel. Clausen v. Lab. Corp. of America, Inc.*, "Rule 9(b)'s directive that 'the circumstances constituting fraud or mistake shall be stated with particularity' does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government." 290 F.3d 1301, 1311 (11th Cir. 2002) (cited with approval by *Greenfield*, 880 F.3d at 98 n.9).

Here, the government identifies a list of 30 claims for Copaxone that were supported by foundation payments, including the date and amount of the foundation payments. (Compl. Ex. 79.) This list lacks the critical detail needed to establish FCA causation—that Teva was the source of the foundation payment for a particular claim. Indeed, the lack of an established line is exacerbated by the fact that TAF's and CDF's MS funds were supported by donations from other drug manufacturers and supported multiple medications. (Compl. Exs. 8, 55, 64.) Thus, the patients whose claims are listed in Exhibit 79 could have instead received funds from those other

---

medical care received, there must be a causal link "between the alleged kickbacks and the medical care received by at least one of [the identified] federally insured patients." *Medco*, 880 F.3d at 100. Without that link, the government's allegations fall short of the causation section 1320a-7b(g). *See id.*

donors. Likewise, Teva's donations may have benefited the purchase of other MS medications. (Compl. Ex. 45 at 1 ("Because this is a Disease State Fund some of our patients could receive funds from other donations other then [*sic*] ours which we believe occurred in 2009."); Compl. Ex. 25 ¶ 3(b) ("Donor will not be the sole pharmaceutical manufacturer solicited for funding of the Foundation or the Program."); Compl. Ex. 2 ¶ 9 (information for patients seeking charitable financial assistance for Copaxone and other MS medications were intentionally grouped together and sent simultaneously to charities).) In other words, in the absence of an indication that Teva's donations are linked to a particular claim, the government does not "rule out the chance" that the Copaxone patients received support through funds provided by other manufacturers. And thus, there is no connecting causal link. *Booker,* 847 F.3d at 57.

And while temporal proximity is not enough, *Medco*, 880 F.3d at 100, the government fails to even plead that. The Complaint's exhibits reflect that a significant temporal gap existed between when Teva donated to charities, (*see* Compl. Ex. 1), and when charities provided financial grants to many Copaxone patients. (*See id.* Ex. 79.) During these intervening periods (which often were weeks or months), other donors might have provided funds to the charities' pools that went to Copaxone patients and/or Teva's donations might have been depleted by covering non-Copaxone patients. The government's allegations do not rule out these plausible possibilities.

Teva's knowledge that its donations could cover Copaxone patients, and its hope and expectation that they would, is irrelevant to whether one of the 30 claims identified by the government is actually "linked" to those donations, as opposed to the donations of another MS treatment manufacturer. The government's argument is no different than the "taint of a kickback" argument that the *Greenfield* court rejected, and it should be rejected here if raised.

C. The Government Fails to Allege a Conspiracy to Violate the False Claims Act.

In threadbare fashion, the government claims that (i) Teva, CDF, and ACS and (ii) Teva, TAF, and ACS conspired to violate the FCA. (Compl. ¶¶ 129-132.) But the government has not satisfied its pleading burden under Rule 9(b) to state a claim for conspiracy to violate the FCA, 31 U.S.C. § 3729(a)(1)(C), because it has alleged no facts—let alone facts sufficient under 9(b)—to show a "meeting of the minds" to defraud the government involving either charity, CDF or TAF. *See United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009) (holding that Rule 9(b) applies to FCA conspiracy claims); *see also United States ex rel. Atkinson v. Pa. Shipbuilding Co.*, No. 94-7316, 2004 U.S. Dist. LEXIS 14532, at *15 (E.D. Pa. July 28, 2004) (a conspiracy to violate the FCA requires a "meeting of the minds") (citations and quotations omitted); *United States v. Toyobo Co.*, 811 F. Supp. 2d 37, 51 (D.D.C. 2011) (granting motion to dismiss where "the complaint is devoid of factual allegations that support the inference that [defendant] and the vest manufacturers entered into any agreements for the purpose of getting the government to pay a claim"); *United States ex rel. McGee v. IBM Corp.*, 81 F. Supp. 3d 643, 666 (N.D. Ill. 2015) (granting motion to dismiss where "[relator] fails to allege anything that would allow the Court to reasonably infer that [defendant] had an agreement with anyone, let alone what the terms of that agreement were").

The government does not allege any facts that anyone from either CDF or TAF agreed with anyone at ACS or Teva to submit false claims to the government. Rather, the government's particularized allegations involving CDF and TAF are limited to allegations that CDF and TAF shared with Teva the amount of money that each foundation provided to Copaxone patients (Compl. ¶¶ 80, 81), Teva received enrollment data from CDF and TAF via ACS (*id.* ¶¶ 82, 86) and that CDF and TAF were willing to accept "batch" enrollment files from ACS (*id.* ¶ 77).

None of these actions suggest a conspiracy, let alone constitute particularized facts to show a meeting of the minds to defraud the government. As set forth above, the per-patient donation amount is a function of the Medicare Part D "coverage gap" and therefore is readily identifiable. *See supra* at IV.A.1.c. Moreover, there is nothing illegal about the acceptance of "batch" enrollment files. *See supra* at IV.A.1.b.[26] And none of the facts alleged undermine the definitive independence that the charities ultimately had, and exercised, over the distribution of Teva's (and other manufacturers') donations. The government's conspiracy claim therefore fails and should be dismissed.

D. The Government's Unjust Enrichment Claim Should Be Dismissed.

The government's unjust enrichment claim fails for similar reasons. Unjust enrichment is an equitable remedy that does not lie where there is an adequate remedy at law. *See, e.g.*, *United States v. Job Res. For Disabled*, No. 97 C 3904, 2000 WL 562444, at *4 (N.D. Ill. May 9, 2000) ("Equitable remedies are only appropriate if no adequate legal remedy exists. [The Court] find[s] the False Claims Act to be an adequate legal remedy to protect the federal government's interests (whether the claim prevails in the end or not, it is adequate)."). While the government may plead causes of action in the alternative, where the government cannot satisfy the statutory elements under the AKS and the FCA, the Court should not permit the government to seek relief beyond

[26] The government does not plead a separate conspiracy involving only Teva and ACS, but even if it had, such a claim would fail as well. The government's affidavit from an ACS employee shows that Teva's employee Lynch expressly avoided asking for information that was contrary to the OIG's prophylactic guidance. (Compl. Ex. 2.) Therefore, the government has alleged no particularized facts that demonstrate an agreement between Teva and ACS to violate the OIG guidance, let alone the FCA. *See, e,g.*, *United States ex rel. Kasowitz Benson Torres LLP v. BASF Corp.*, 285 F. Supp. 3d 44, 56 (D.D.C. 2017), *aff'd*, 929 F.3d 721 (D.C. Cir. 2019) ("there can be no liability for conspiracy where there is no underlying violation of the FCA.").

what Congress has declared to be unlawful. To do so would abrogate the statutory requirements that Congress has set forth.

Moreover, as set forth above, the government has not alleged any unlawful or unjust conduct. Thus, even if the government is allowed to plead unjust enrichment in the alternative, the claim should be dismissed. The Complaint fails to state a claim for unjust enrichment because Teva did not receive a benefit that would be unjust for it to retain. To plead a cause of action of unjust enrichment, the government must allege facts showing: "(1) a benefit conferred upon the defendant by the plaintiff; (2) an appreciation or knowledge by the defendant of the benefit; and (3) acceptance or retention by the defendant of the benefit under circumstances that would be inequitable without payment for its value." *Taylor v. Moskow*, No. CIV.A. 13-12675-FDS, 2014 WL 2573990 at *5 (D. Mass. June 6, 2014) (*citing Mass. Eye & Ear Infirmary v. QLT Phototherapeutics, Inc.*, 552 F.3d 47, 57 (1st Cir. 2009). "Conclusory statement[s]" are insufficient to save an unjust enrichment claim from dismissal. *Koufos v. US Bank, N.A.*, 939 F. Supp. 2d 40, 52 (D. Mass 2013).

Aside from the conclusory allegation that Teva was unjustly enriched "because of illegal inducement Teva paid to Medicare patients via CDF and TAF" (Compl. ¶ 134), the Complaint does not provide a link between Teva's donations and any payment by the government for Copaxone. Teva's donations were made through an independent charity that retained ultimate control over how the funds were distributed, *see supra* at IV.A.1.b, and Teva did not induce or reward any prescribers or patients to use Copaxone. When the OIG recognized the coverage gap problem caused by Medicare Part D, it informed the health-care industry: "that pharmaceutical manufacturers can effectively contribute to the pharmaceutical safety net by making cash donations to independent, bona fide charitable assistance programs." 2005 OIG Guidance, 70

Fed. Reg. at 70623. This included donations known to support the donors own products, including single drug charitable funds. 2005 OIG Guidance, 70 Fed. Reg. at 70627 n.19. Undoubtedly, it was the ***expectation*** of the government, charitable foundations, and drug manufacturers that when drug manufacturers donated to charitable assistance funds that covered the donor's products, the donor likely would receive a financial benefit. As a result, Teva has received no "unjust" benefit. *See Cmty. Builders, Inc. v. Indian Motocycle Assocs., Inc.*, 692 N.E.2d 964, 979 (Ma. 1998) ("Unjust enrichment, as a basis for restitution, requires more than benefit. The benefit must be *unjust*, a quality that turns on the reasonable expectations of the parties.") (emphasis in original). The government's unjust enrichment claim should therefore be dismissed.

E. Teva's Communications with TAF and CDF are Protected Under the First Amendment as "Charitable Solicitations."

The government's litigation against Teva is an impermissible attempt to restrict speech between Teva and charitable foundations, and is therefore violative of the First Amendment. As "fully protected speech," *Bd. of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 474 (1989), a charitable solicitation is protected "whether or not any speech incident to the solicitation actually takes place, because a sufficient nexus exists between a charity's expression of ideas and its fundraising." *Speet v. Schuette*, 726 F.3d 867, 877 (6th Cir. 2013). The highest level of scrutiny applies "to laws restricting the solicitation of contributions to charity, upholding the speech limitations only if they are narrowly tailored to serve a compelling interest." *Williams-Yulee v. Fla. Bar,* 575 U.S. 433, 442 (2015); *see also Riley v. Nat'l Fed'n of the Blind of N. C., Inc.,* 487 U.S. 781, 789, 796 (1988).

The restriction the government seeks to impose in this case is one that applies ***only*** to

pharmaceutical manufacturers. Companies other than pharmaceutical manufacturers are free to receive data and communications, like those at issue here, from charitable foundations, while according to the government, Teva and other similarly situated pharmaceutical manufacturers cannot. Because these restrictions are based on the identity of the speaker, and based on the content of the speech (*e.g.*, data from charitable foundations), the government must overcome a presumptive invalidity of the restriction. *See Sorrell v. IMS Health, Inc.*, 564 U.S. 552, 571-72 (2011) ("Under a commercial speech inquiry, it is the State's burden to justify its content-based law as consistent with the First Amendment."); *see R.A.V. v. City of St. Paul,* 505 U.S. 377, 382 (1992) ("Content-based regulations are presumptively invalid"); *Barr v. Am. Ass'n of Political Consultants*, 140 S. Ct. 2335, 2347 (2020) (Congress may not disfavor speech "'directed at certain content and … aimed at particular speakers'") (quoting *Sorrell*).

Because the government's unbounded theory of AKS liability would effectively criminalize speech incident to charitable giving, principles of constitutional avoidance counsel in favor dismissal here. *See, e.g.*, *Clifton v. Fed. Election Comm'n*, 114 F.3d 1309, 1315 (1st Cir. 1997) (noting that courts have the long-standing practice of narrowly construing statutes to avoid constitutional issues).

V. CONCLUSION

For the foregoing reasons, Teva respectfully requests that the Court dismiss the Complaint with prejudice.

Dated: October 19, 2020

Respectfully Submitted,

/s/ Emily Renshaw

Emily Renshaw (BBO #675316)
Morgan, Lewis & Bockius LLP
One Federal Street
Boston, MA 02110-1726
Tel: 1.617.951.8000
emily.renshaw@morganlewis.com

Eric Sitarchuk (admitted *pro hac vice*)
Alison Tanchyk (admitted *pro hac vice*)
Rebecca J. Hillyer (admitted *pro hac vice*)
William T. McEnroe (admitted *pro hac vice*)
Morgan, Lewis & Bockius LLP
1701 Market Street
Philadelphia, PA 19103-2921
Tel: 215.963.5000
eric.sitarchuk@morganlewis.com
alison.tanchyk@morganlewis.com
rebecca.hillyer@morganlewis.com
william.mcenroe@morganlewis.com

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was served upon all counsel of record via ECF electronic filing on October 19, 2020.

/s/ Emily Renshaw
Emily Renshaw (BBO #675316)